

### **REMARKS**

The Applicant requests that the above Amendment be entered and the application be examined as amended and in view of the remarks below.

By this Amendment the Applicant amended claim 1 to delete the dashes and amended claim 10 to remove an unnecessary comma. The Applicant also introduced new claims 11-16. Support for the inventions recited in new claims 11 and 12 appears, for example, on page 8, lines 26-28 and in Figure 11 of the as-filed application. Support for the invention recited in new claim 13 appears, for example, on page 3, lines 22-25 and in Figure 11. Support for new claim 14 appears on page 6, lines 7-10. Support for new claims 15-17 appears on page 4, line 19 to page 6, line 2. No new matter was introduced.

Claims 1-17 are now pending in this application.

#### **I Response to Obviousness Rejection Based upon Marnay**

On pages 2 and 3 of the Action, the Patent Office rejected claims 1-9 pursuant to 35 U.S.C. §103(a) as obvious in view of the teachings of PCT Publication WO2001/01893 of Marnay, et al. [herein "Marnay"]. The Applicant acknowledges with appreciation the Patent Office's identification of corresponding US Patent 6,936,071 of Marnay, et al. The Applicant respectfully submits that these rejections are inappropriate and requests that these rejections be reconsidered and withdrawn based upon the following comments and observations.

##### **I-A The Guidance of the Supreme Court on "Obviousness"**

In its recent decision in *KSR v. Teleflex, Inc.*, the Supreme Court of the United States underscored the continued significance of the *Graham* inquiries when presenting a proper rejection under 35 U.S.C. §103(a), that is,

- (a) determining the scope and contents of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating evidence of secondary consideration.

In addition, the Court held that in support of a rejection under 35 U.S.C. § 103(a) should be made explicit, and that it was important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements “in the manner claimed.”

The Court specifically stated:

Often, it will be necessary...to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**. *KSR*, slip op. at 14 (emphasis added)

Therefore, in formulating a rejection under 35 U.S.C. § 103(a) based upon prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have modified the prior art elements in the manner claimed.

The Applicant submits that the Supreme Court’s guidance is particularly applicable to the present rejections under §103(a). In particular, among other things, the Applicant submits that there is no “apparent reason” to modify the teachings of the cited reference to yield the present invention and therefore these rejections are inappropriate.

With regards to the present rejection of claim 1 and its dependents, as discussed further below, not only does Marnay not disclose the present invention, but there is no apparent reason to modify the teachings of Marnay to provide the invention recited in claim 1 and its dependents.

**I-B Brief Review of Invention: “posterior vs. anterior”**

As recited in claim 1, the present invention is a “postero-lateral intervertebral disc prosthesis.” As is known in the art, a “postero-lateral” disc prosthesis is a prosthesis that is designed to be inserted by the surgeon between vertebral discs by way of the “back” or “posterior” of the spine of the patient, for example, by way of an incision in the abdomen. In contrast, an “antero-lateral” prosthesis is designed to be inserted by the surgeon between vertebral discs by way of the “front” or “anterior” of the spine. For example, The American Heritage® Medical Dictionary, Copyright © 2007, 2004 by Houghton Mifflin

Company, provides the following definitions:

**posterolateral**, *adj.* In back and away from the middle line.

and

**anterolateral**, *adj.* In front and away from the middle line.

As described in the “Background” section of the present application, see paragraphs [0009] through [0016] of published application US 2008/0015699, various prior art “solutions” have been proposed for “anterior route” insertion of disc prosthesis, but these solutions have disadvantages because they are not designed to be inserted into the spine by accessing the spine from the front or abdomen of the patient. In contrast, as described in paragraph [0017], aspects of the present invention overcome the disadvantages of prostheses that are not designed for insertion “posteriorly” of the spine, that is, from the front of the patient.

As described in paragraphs [0017] and [0018] (again, from the US Publication),

[0017] Starting out from this prior art, one of the problems that the invention sets out to solve is, first, to make a disc prosthesis that is **small enough in size and that functions in a manner close to physiology**; and, second, to implant this prosthesis **by a new posterior approach route**. [Emphasis added.]

[0018] According to the invention, the disc prosthesis **is round** and has a diameter which is less than 30 mm in order **to be able to be inserted by a posterior route**, given that the nerve elements - dural sac, roots, and also vessels - **do not make it possible to fit a larger prosthesis at this location**. [Emphasis added.]

Furthermore, as described in paragraphs [0080] through [0085] of the published application,

[0080] The advantages are clearly apparent from the description, in particular we emphasize and remind the reader of:

[0081] - the possibility of introducing the prosthesis by a **posterior route**, taking into account the **minimum dimensions and its generally circular shape**; it is consequently

placed by a **postero-lateral route** and is perfectly centred by fluoroscopic marking;  
[Emphasis added.]

[0082] - compliance with physiology, given that the prosthesis has a centre of rotation that permits flexion and antero-posterior and medio-lateral translation;

[0083] - the possibility of **posterior** opening of the lumbar canal to fit the prosthesis, permitting curetage of the associated compression elements, which can be cureted **only by this posterior route**: narrow canal, disc hernia, osteophytes. [Emphasis added.]

[0084] - **the use of the posterior route** allows the plexus elements to be respected in order not to dissect the large vessels or the ureter, which **may be injured by the anterior approach routes used in the prior art**; [Emphasis added.]

[0085] this prosthesis allows one to conserve the articular processes by osteotomizing them and re-fixing them according to a specific protocol.

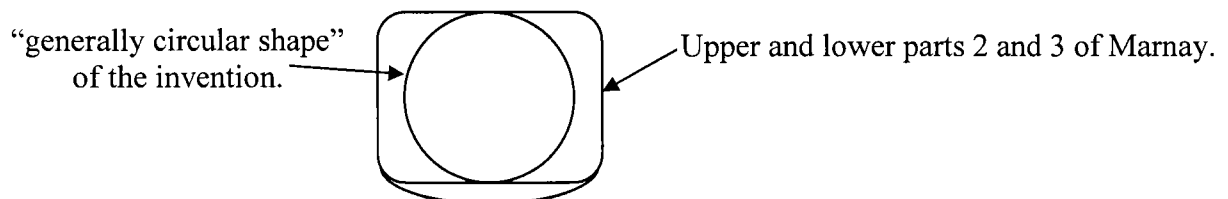
As is known in the art, due the presence of spinal structures, such as, spinal facets, some bone removal, or “facet osteotomy,” typically must be performed to provide posterior access to the spinal disc. An example of this osteotomy is provided in the description in paragraphs [0024] through [0039] and illustrated in Figures 1-4 of the present application. In particular, Figure 1 illustrates in dark lines one preferred osteotomy, or cuts in the spinal facets, that may be made, and Figure 3 illustrates the osteotomy with the bone fragments removed to allow posterior access to the disc, for example, in a direction from right to left in Figure 3.

Aspects of the present invention are specially designed to be introduced to the spinal column from the posterior of the spine, for example, through the facets shown on the right in Figures 1 and 3. It will be apparent to those of skill in the art that the prostheses of the existing art, including Marnay, cannot be inserted in the spine by a surgeon by the posterior route. Only the present invention even recognizes the potential for accessing the spine by means of the posterior route, and only the present invention provides a disc prosthesis amenable to insertion through the posterior route.

**I-C Response to Rejection of claim 1 Based upon Marnay**

In support of the present rejection, the Patent Office cites Figure 1 of Marnay and asserts that implant 1 of Marnay constitutes a “postero-lateral intervertebral disc prosthesis” as recited in claim 1. However, the Applicant respectfully submits that based upon the characteristics, function, and mode of insertion of a “postero-lateral prosthesis,” for example, as discussed in section 1-B above, there is no teaching or suggestion whatsoever in Marnay that implant 1 is, or can be, a “postero-lateral prosthesis.” For example, by its very appearance with broad, sharp-angled “upper” and “lower parts” 2 and 3, and the course, serrated projections 6 and 14, the Marnay device clearly is not intended to pass through the limited space and delicate tissues that characterize the posterior route, as is the claimed invention. Based upon these distinctions alone, this rejection of claim 1 as obvious in view of Marnay is untenable and must be withdrawn.

Moreover, contrary to the claimed invention, the implant 1 of Marnay does not comprise “first and second inserts have a generally circular shape in the form of a disc.” As shown most clearly in Figures 1-4, parts 2 and 3 of Marnay, which have been associated by the Patent Office with the claimed “inserts,” are not circular in shape. In the middle of page 3 of the Action, the Patent Office contends that Marnay’s parts 2 and 3 “are generally circular (the implant is round, see fig 1 below).” However, in contrast, Figure 1 does not show “round” parts; Figure 1 of Marnay (and every other figure of Marnay) illustrates rectangular parts with straight, uncurved sides. The contrast in shapes is clearly illustrated below.



The Applicant submits that such “rectangular” parts are clearly not “generally circular” and are not intended “to permit introduction of the prosthesis by a postero-lateral approach route” as recited in claim 1.

With regard to the guidance of the Supreme Court in *KSR*, not only does Marnay not disclose or suggest a “postero-lateral intervertebral disc prosthesis” and also does not disclose or suggest “generally circular inserts,” but there is no “apparent reason” to modify the teachings of Marnay to provide the invention recited in claim 1. For example, failing to even recognize that a disc prosthesis can be inserted by the “posterior route,” one of skill in the art would not have a reason to modify the prosthesis of Marnay for insertion by means of the posterior route.

Moreover, failing to recognize the limited space available for posterior insertion, there would be no apparent reason to modify Marnay to provide “generally circular inserts.”

In addition, at 4:36-67 Marnay teaches that blind bores 20 and 21 are provided in “legs” 16 and 17 of Marnay “to serve as receptacles for pinlike extensions of a manipulation instrument.” This suggests that the rectangular shape of the Marnay device is required to provide space for these bores for proper insertion by the manipulation instrument. Again, there would be no reason to change the rectangular shape, and, if changed, the Marnay device would not be compatible with the “extensions of the manipulation instrument” as taught by Marnay.

Accordingly, for all these reasons, the Applicant respectfully requests that this rejection of claim 1 as obvious in view of Marnay be reconsidered and withdrawn.

**I-D Response to Rejection of Dependent Claims Based upon Marnay**

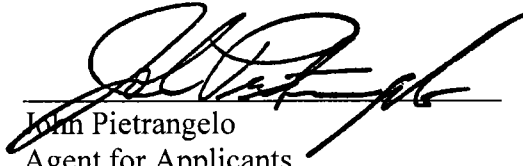
With respect to the rejections of dependent claims 2-9, the Applicant submits that these claims are not obvious in view of Marnay for the same reasons that claim 1, from which they depend, is not obvious. The Applicant respectfully requests that these rejections be reconsidered and withdrawn.

**II CONCLUSION**

The Applicant believes that the above Amendment and Remarks place the application in allowable form. An early and favorable action on the merits of the application is requested.

If a telephone conference would be of assistance in advancing prosecution of the subject application, the Applicant's undersigned Agent invites the Examiner to telephone him at the number provided.

*Respectfully submitted,*

  
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